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**TABLE OF CONTENTS Page**

1. References 2

2. Scope 3

3. Purpose 3

4. Background 3

5. Definitions and Acronyms 3

6. Apparatus 3

7. Risk Assessment 4

8. Experiment Design / Sample Size Justification 5

9. ZIP Pen Procedure 5

10. Acceptance Criteria 8

11. Appendix I: Hand Switching Device Fluid Ingress Test Setup Cable 10

12. Appendix II: Hand Switching Device Fluid Ingress Test Form 12

# References

|  |  |
| --- | --- |
| IEC 60601–2–2: 2009 | Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories |

# Scope

This protocol pertains to the Zip Pen Catalog numbers 2525-10, 2525-10EC, 2525-10BN, 2525-10ECBN, 2525-15, and 2525-15EC. For these tests, the four catalog numbers are considered equivalent and either may be tested to represent the other.

# Purpose

The purpose of this test protocol is to specify testing required on the Zip Pen with improved seal on the PCB to show compliance with IEC60601-2-2: 2009. The protocol will be run on both gamma sterile and EO exposed product.

# Background

The Zip Pen is a smoke evacuation pencil that has been sold as a sterile product for approximately two years. The original Zip Pen validation tested for fluid ingress passed, see test report ENG-RPT-331. During a qualification for Zip Pen sterilized by EO there were fluid ingress failures. Because of these failures an improvement project was created. This testing is for the product with the improvements. The improved components and their drawing revisions are as follows:

X5800103-01 Rev 003C PCB Overmold

X4010337-01 Rev A PCB

X5800096-01 Rev 003B Carriage

# Definitions and Acronyms

|  |  |
| --- | --- |
| N/A |  |

# Apparatus

### Ohmmeter (or multi-meter)

### 0.9% Saline solution

### TDS 2014 Tektronix Oscilloscope, or equivalent

### Appropriate leads for connection of the test set-up

### Stop watch or equivalent

### Container to support device and hold 1 Liter of fluid

### Function Generator

### Current Loop

# Risk Assessment

## The FMEA in ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risk associated with fluid ingress. The highest severity rating is 10 for patient burn attributable to incorrect mode activation or self activation. Note that test results indicate that incorrect mode activation or self activation do not occur as a failure mode for the Zip Pen. The failure manifests as the button not working and no output occurs. The failure modes, cause, mitigation and verification listed in the FMEA are as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| Failure Mode | Cause | Mitigation | Verification |
| Self Activation | Fluid enters housing causing short circuit to internal components | Pencil designed to prevent short circuit due to fluid ingress, material and supplier selection and product validation | Material, design and assembly requirements are defined on drawing.  Fluid Ingress Test Report based on this protocol. Report number is ENG-RPT-555 |

# Experiment Design / Sample Size Justification

## The product improvement test samples will be sterilized with either Ethylene Oxide gas for two periods of 4 hours each or by gamma irradiation for a minimum of 50 kGy. Both sterilization methods will be tested. These exposures simulate the worst case exposure that the product may see in sterilization.

## Test samples will not be subjected to accelerated aging. Rationale for this decision is that there are no new materials being introduced in the product. The added overmold seal at the front of the PCB is the same construction as the seal at the back of the PCB that has been previously tested.

## Prior to evaluation, the samples will be subjected to a shipping and storage cycle, preconditioning and transit testing.

## A sample size of 68 is justified based on the use of a C = 0 sampling plan which uses a lot size of up to 10,000 and an AQL of 0.65. This AQL is based upon a critical defect classification (per QA-SOP-012). The sample will be split into two groups of 34, one for EO sterilization and one for gamma sterilization. (For convenience due to the number of samples per box, 80 samples will be sterilized, and may be split into two groups of 40.)

## As an investigation to prove that the sterilization method does not influence the failure mode, non-sterile product that has not been improved will be tested. The results of this testing will be included in the test report. If the non-sterile product does not exhibit the failure mode, the sample size of the improved product in step 8.4 above will be increased to 68 units of each sterilization type.

## A summary of the experimental design is as follows:

Sterilization exposure, either EO or Gamma

Shipping and storage cycle and preconditioning

Transit test

Continuity Measurement

Handpiece Fluid Ingress Test

# ZIP Pen Procedure

## This procedure will be performed separately for each sterilization treatment and for the non-sterile product.

## Perform the shipping and storage cycle, preconditioning and transit test per ENG-PRT-229 paragraphs 12 and 13. Document these activities in the test report.

## Document the manufacturer, model number, and calibration information for all equipment used throughout this procedure.

## Assign each sample a unique identification and record on the sample with permanent marker or other permanent method.

## Prior to testing, use an ohmmeter to measure and record the resistance of each Zip Pen. Check both Cut and Coag switches. A device is considered out of tolerance if the resistance is greater than 50 ohms when the button is depressed or less than 10,000 ohms when the button is released. Do not use an out of tolerance Zip Pen for testing.

## Appendix I shows the setup used for fluid ingress testing. Place the function generator, current loop, oscilloscope, 1 liter saline solution, stop watch, and container on workbench.

## Turn on function generator and set for 10 Vp-p and 1 kHz.

### Ensure the offset = 0

### Ensure the waveform is sinusoidal.

## Connect one end of a coax cable to the connector of the current loop. Connect the other end of the coax to channel 1 on the oscilloscope (make sure channel 1 is set to read a 1x probe). When measuring current with the loop, voltage is displayed on the oscilloscope as a 1 to 1 correlation (1 amp = 1 volt)

## Turn the oscilloscope on and set the display to show 250 ms/division and 5 mV/division.

## Set the cursors on the oscilloscope to be ± 2.5 mV or as close to this setting as possible.

## Using the trigger menu, set the *Slope* to “Rising” and the *Mode* to “Normal”.

## Set the trigger point to approximately 2.5 mV using the trigger knob.

## Connect the appropriate lead to the function generator.

## Place the Zip Pen to be tested in the container with the cord and plug out of the container.

## Using the test lead identified in 10.12, connect one wire to the common pin on the Zip Pen plug and the other wire to the cut or coag pin on the plug (depending on which mode is being tested).

## The wire connected to the plug’s common pin must go through the current loop before connecting to the pin.

## Center the signal on the oscilloscope around the center line, i.e. 0 Volts.

## Verify that the signal is between the cursors, or is less than or equal to ± 2.5 mV. If not, mark the sample as defective, remove it from the test and replace with a new sample.

## Disconnect the test lead from the current activation pin (cut or coag) and connect to the remaining activation pin on the plug (cut or coag).

## Verify that the signal is between the cursors, or is less than or equal to ± 2.5 mV. If not, mark the sample as defective, remove it from the test and replace with a new sample.

## With the test cable connected, hold the Zip Pen handle horizontally at least 2 inches above the bottom of the container with the buttons on top.

## Pour 1 liter of 0.9% saline over the Zip Pen housing during a 15 second interval so that it wets the entire length of the handle.

## Allow the fluid to drain away freely.

## Immediately press the button of the mode being tested and release. After the button release measure the voltage value at 500 ms on the oscilloscope.

### The voltage should be between the cursor lines, or less than or equal to ± 2.5 mV.

### When the button on the Zip Pen is pressed, the voltage on the screen should go up. The signal should extend past the cursors.

### After the button is released, the voltage should drop to less than or equal to ± 2.5 mV. The time is measured beginning from the last high point, before it drops.

## Repeat steps 9.22 through 10.23 nine more times.

## Record in Appendix II if the sample passed or failed (i.e. measured between the cursor lines at the 500 ms mark or not).

## Change the test cable connection on the Zip Pen plug to measure the remaining mode.

## Repeat 9.22 through 9.24 for the remaining mode.

## Repeat all steps, 9.12 – 9.26 for each sample.

# Acceptance Criteria

## The device is considered acceptable if, after applying saline, the button can be operated 10 times with the current being less than or equal to 2.5 mA (measured as 2.5 mV on the oscilloscope) at a time period of 0.5 seconds after the button is released. (The standard requires the AC impedance of the switch to exceed 2.0 kW within 0.5 seconds after release. Using a voltage of 10 Vp-p, a current of 5.0 mA or less is necessary to meet this requirement).

# Appendix I: Hand Switching Device Fluid Ingress Test Setup Cable

Function Generator

Container

Oscilloscope

# Appendix II: Hand Switching Device Fluid Ingress Test Form

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample #** | **CONTINUITY** | | **FLUID INGRESS (pass/fail)** | |  | **Calibration Information:** | |
| **CUT** | **COAG** | **CUT** | **COAG** |  | ***Function Generator*** | |
| 1 |  |  |  |  |  | Megadyne #: | |
| 2 |  |  |  |  |  | Calibration Date: |  |
| 3 |  |  |  |  |  | Calibration Due: |  |
| 4 |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  | ***Multimeter*** |  |
| 6 |  |  |  |  |  | Megadyne #: |  |
| 7 |  |  |  |  |  | Calibration Date: | |
| 8 |  |  |  |  |  | Calibration Due: |  |
| 9 |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  | ***Current Loop*** |  |
| 11 |  |  |  |  |  | Megadyne #: |  |
| 12 |  |  |  |  |  | Calibration Date: |  |
| 13 |  |  |  |  |  | Calibration Due: | |
| 14 |  |  |  |  |  |  |  |
| 15 |  |  |  |  |  | ***Oscilloscope*** |  |
| 16 |  |  |  |  |  | Megadyne #: |  |
| 17 |  |  |  |  |  | Calibration Date: |  |
| 18 |  |  |  |  |  | Calibration Due: |  |
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Operator Name Operator Signature Date completed